IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPELLANTS:	Clasbrummel et al.	CONFIRMATION NO. 4762
SERIAL NO.:	10.036,618	GROUP ART UNIT: 2125
FILED:	December 21, 2001	EXAMINER: Carlos R Rodriquez Ortiz
TITLE:	"METHOD AND APPARATUS FOR PREPARING AN ANATOMICAL IMPLANT"	

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Commissioner for Patents
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APPELLANTS' MAIN APPEAL BRIEF

S I R:

In accordance with the provisions of 37 C.F.R. §1.192, Appellants herewith submit their main brief in support of the appeal of the above-referenced application.

REAL PARTY IN INTEREST:

The real party in interest is the assignee of the present application, Siemens Aktiengesellschaft, a German corporation.

RELATED APPEALS AND INTERFERENCES:

There are no related appeals and no related interferences.

STATUS OF CLAIMS:

Claims 1-10 are the subject of the present appeal and constitute all pending claims of the application.

STATUS OF AMENDMENTS:

This Brief is accompanied by an Amendment (Amendment "B") to make an editorial change in claim 1 to correct a typographical error therein. Since this Amendment is being filed simultaneously with the present Brief, as yet there has been no action regarding entry of this Amendment, however, in view of the purely

editorial nature of the Amendment, Appellants will assume that it satisfies the requirements for entry after the final rejection under 35 U.S.C. §116, and the copy of claim 1 in the Appendix attached to this Brief embodies the change in claim 1 made in Amendment "B". No changes to any other of the claims was made in Amendment "B".

GROUPING OF CLAIMS:

The patentability of claims 1-6 stands or falls together. The patentability of each of claims 7, 8, 9 and 10 stands or falls independently of any other claim on appeal, and separate arguments are provided below for the independent patentability of each of claims 7, 8, 9 and 10.

SUMMARY OF THE INVENTION:

The subject matter of the claims on appeal concerns a method and an apparatus for preparing an anatomical implant wherein the acquisition of the data needed for preparing the implant, as well as the actual preparation of the implant, proceed intra-operatively during the same medical interventional procedure.

The inventive apparatus shown in the figure has a movable C-arm x-ray apparatus 1. (p4., l.22-23) The C-arm x-ray apparatus 1 has an apparatus carriage 3 provided with wheels 2 in which a lifting mechanism 4 that includes a column 5 (schematically indicated in the figure) is arranged. A holder 6 at which a support device 7 for a C-arm 8 is present is arranged at the column 5. Displaced on the C-arm 8 opposite one another are an x-ray source 9 which emit a cone-shaped x-ray beam, and an x-ray receiver 10. (p4., l. 23 - p.5, l.4)

The C-arm x-ray apparatus 1 shown in the Figure allows a 3D dataset of a body part of a patient P borne on a patient support 11 to be prepared. (p.5, l.5-6) In

the exemplary embodiment, an image computer 12 connected to the x-ray receiver 10 (in a way not shown) is arranged in the apparatus carriage 3 for this purpose. (p.5, l.6-8) In a known way, the image computer 12 can reconstruct a 3D dataset of the body part to be portrayed from a series of 2D projections acquired with the x-ray source 9 and x-ray receiver 10 that are acquired by an adjustment of the C-arm 8 around a body part of the patient P to be presented in an image. (p.5, l.8-12) The C-arm 8 is motor-adjusted by approximately 190° either along its circumference around the orbital axis A (schematically indicated in the figure) or around the angulation axis B, (also schematically indicated in the figure), whereby approximately 50 through 100 2D projections of the body part of the patient P are acquired during the adjustment. (p.5, l.12-16) Since the position of the C-arm 8 is identified with the assistance of distance sensors 13, 14 for each of the 2D projections, the projection geometries can be identified for each 2D projection of the series of 2D projections, these projection geometries being required for the reconstruction of a 3D dataset of the body part of the patient P. (p.5, l.17-21) In the exemplary embodiment shown in the figure, a 3D dataset of the skull S of the patient P, which exhibits a fault D schematically indicated in the figure, has been acquired by adjustment of the C-arm 8 around the angulation axis B. (p.5, l.21-24) Using known methods, 2D images or 3D images of the skull S of the patient P can be produced from the 3D dataset, these images being displayed on a display device 15 connected to the image computer 12. (p.5, l.24 - p.6, l.2) Moreover, the fault D, whereby is a opening of the skull S, can be measured on the basis of the 3D dataset of the skull S of the patient P, so that the image computer 12 can generate a dataset that has the dimensions and shape of an implant I covering the fault. (p.6, l.2-5) The measuring is initiated, for example, by a

physician, who marks the fault in 2D images or in a 3D image with input unit, for example, a joy stick (not shown), connected to the image computer 12. (p.6, l.5-8)

The implant I is intra-operatively produced, so that the measurement of the fault D can occur, the implant I can be produced and, following thereupon, the fault D can be eliminated by introducing the implant I into the skull S of the patient P in one operation. (p.6, l.9-12) In the exemplary embodiment, two fabrication devices 20, 30 are provided for the intra-operative production of the implant I, these two fabrication devices 20, 30 being connected to the image computer 12 of the C-bend x-ray device 1 via data cables 21, 31. (p.6, l.12-15) The fabrication device 20 in the case of the present exemplary embodiment is a device with which an implant can be fabricated from a blank by material removing methods such as lathing, milling and drilling. (p.6, l.15-17) The fabrication device 30, in contrast, is a device with which an implant I can be formed from a blank R with laser beams. (p.6, l.17-19)

In the exemplary embodiment, the dataset generated by the image computer 12, this dataset describing the dimensions of the implant I for introduction into the skull S of the patient P, is communicated via the data cable 31 to a control computer 32 of the fabrication device 30. (p.6, l.20-23) This drives a laser device 33 that produces the implant I from the blank R with laser beam 34 on the basis of the dataset. In a known way, the implant I is thereby composed of a physiologically compatible material. (p.6, l.23 - p.7, l.2)

Finally, the implant I produced on basis of the 3D dataset can be introduced directly into the skull S of the patient P for the elimination of the fault D intra-operatively, i.e. in the same operation. (p.7, l.3-5)

ISSUES ON APPEAL:

The following issues are the subject of the present appeal:

Whether the subject matter of claims 1-6 would have been obvious to a person of ordinary skill in the art under the provisions of 35 U.S.C. §103(a) based on the teachings of United States Patent No. 4,436,684 (White) in view of the teachings of United States Patent No. 6,285,902 (Kienzle, III et al.); and

Whether the subject matter of claims 7-10 would have been obvious to a person of ordinary skill in the art under the provisions of 35 U.S.C. §103(a) based on the teachings of White, Kienzle III et al. and the teachings of United States Patent No. 6,007,243 (Ergun et al.).

ARGUMENT:

In the Office Action dated October 1, 2003, claims 1-6 were finally rejected under 35 U.S.C. §103(a) as being unpatentable over White in view of Kienzle, III et al. The Examiner stated the White reference discloses a method for preparing an anatomical implant which includes the steps of intra-operatively generating a three-dimensional dataset and intra-operatively preparing the implant from the three-dimensional dataset. The Examiner stated the White reference does not disclose the use of a C-arm, as set forth in independent claims 1 and 6, but the Examiner relied on the Kienzle, III et al. reference as disclosing a movable C-arm x-ray apparatus. The Examiner stated it would have been obvious to a person of ordinary skill in the art to modify the apparatus disclosed in the White reference in accordance with the teachings of the Kienzle, III et al. reference, because a person of ordinary skill in the art would have been motivated to do so because C-arms are frequently utilized in the art, especially for computed tomography scans as suggested by

Kienzle III, et al. The Examiner stated a CT scan "is the process of using digital processing to generate a three-dimensional image of the internal of an object of two-dimensional x-ray images."

Appellants respectfully submit this rejection is incorrect for the following reasons. First, Appellants do not agree that the White reference teaches intra-operatively obtaining a 3D dataset of a region of a subject in which an implant is to be implanted, nor does the White reference teach intra-operatively preparing an implant for implantation into the subject. The term "intra-operatively" as used in the claims, and as described in the present specification, means that both of these steps take place during an actual medical interventional, i.e. surgical, procedure for implanting the implant. By contrast, the White reference teaches conducting the scan prior to the surgical operation, and producing the implant prior to the surgical operation. This is one reason why the White reference uses relatively bulky and large CT systems or MRI systems for generating the three-dimensional dataset. Imaging systems of that type cannot be used in an operating room environment. Moreover, in both of those types of imaging systems, the patient proceeds through an opening (actually a tunnel in the case of an MRI system) which would not allow access to the patient by a physician for conducting an interventional medical procedure.

Each of independent claims 1 and 4 was amended during prosecution to add the specific limitation of all steps taking place during a medical interventional procedure. The claims as originally filed already included the requirement of each step taking place “intra-operatively”. The White reference, therefore, clearly does not disclose or suggest method steps or apparatus components which can even serve

as a starting point to obtain a three-dimensional dataset during a medical interventional procedure involving intra-operative steps, nor to produce a medical implant from the 3D image dataset during the medical interventional procedure involving intra-operative steps.

The Examiner's additional reliance on the Kienzle, III et al. reference actually is evidence supporting the non-obviousness of claims 1-6, rather than a basis for justifying a rejection of those claims under 35 U.S.C. §103(a). The Kienzle, III et al. is physically incapable of producing a three-dimensional dataset of a subject, and in fact is only capable of producing, and is only intended to produce, a two-dimensional image. This is explicitly stated at numerous locations in the Kienzle, III et al. reference such as in the third sentence of the abstract. Although the device disclosed in the Kienzle, III et al. reference is referred to as "computer assisted" it is not a computed tomography apparatus, but is instead a fluoroscopic apparatus.

As is well known to those of ordinary skill in the art, for producing a 3D dataset, all known algorithms require that the x-ray source and the detector be able to be rotated around the subject (i.e. around an axis proceeding through the subject) through an angular range of at least approximately 190° (i.e. 180° plus the fan angle of the x-ray beam). The C-arm apparatus disclosed and claimed in the present application is able to do this because the x-ray source and the x-ray detector are mounted at the interior circumference of the C-arm, thereby permitting the outer circumference of the C-arm to be moved through the C-arm holder through the requisite angular range of at least approximately 190°.

Despite the fact that the Kienzle III et al. reference is a fluoroscopy device, and is not used to produce a three-dimensional image, it would not even be

considered by a person of ordinary skill in the art as appropriate for being operable in an attempt to produce a 3D image, because the radiation source and the radiation detector have portions located at the outer circumference of the C-arm, thereby precluding the C-arm from being rotated even through 180°.

Nevertheless, Appellants acknowledge that C-arm x-ray systems have been used in, and are known to be suitable for use in, an operating room environment in order to generate a 3D dataset to produce an image for monitoring the progress of a medical interventional procedure. The Kienzle, III et al. reference, however, is not an example of such a device, and could not be modified for use for such a purpose.

Nevertheless, despite the known use of C-arm x-ray devices for producing a 3D dataset to monitor the progress of a medical intervention, it has heretofore not been known to use such a device to inter-operatively generate a 3D dataset during a medical interventional procedure in order to produce a medical implant from that dataset during the same medical interventional procedure, as disclosed and claimed in the present application. The fact that the Examiner has cited a C-arm device which is incapable of being used in the inventive method or apparatus demonstrates that it is not simply a matter of substituting any sort of C-arm device for the bulky scanner systems disclosed in the White reference. First, a person of ordinary skill in the art must have the insight to realize that it is even possible to produce a medical implant "on the fly" (i.e. during an actual medical procedure for implanting the implant), and then such a person must have enough additional insight to employ an appropriate type of 3D imaging device suited for that particular purpose. It is clear that neither the White reference nor the Kienzle, III et al. reference provides any teachings whatsoever which would assist a person of ordinary skill in the art in

selecting the "right" type of 3D dataset imaging device, and if a person of ordinary skill in the art followed the teachings of White or Kienzle, III et al., such a person would be defeated in producing an operable system because the apparatus and method of the present invention are impossible to achieve based on the teachings of those references. This is because the White reference does not allow intra-operative imaging, and does not teach intra-operative generation of the implant, and the Kienzle, III et al. reference is incapable of three-dimensional imaging, intra-operatively or otherwise.

In the final rejection, the Examiner relied on the Ergun et al. reference, together with the White and Kienzle III et al. references, as a basis for rejecting claims 7-10 under 35 U.S.C. §103(a). Appellants acknowledge that the Ergun et al. reference is an example of a C-arm x-ray apparatus of the type which Appellants acknowledged above to be known to those of ordinary skill in the art, namely a C-arm apparatus capable of executing the necessary range of angular movements so as to allow the acquisition of data for the production of a 3D image. As also noted above, the Kienzle III et al. apparatus is incapable of executing a range of movement that is known to be necessary for acquiring data for the production of a 3D image, and therefore the purpose of retaining the Kienzle III et al. reference in this combination of references for rejecting claims 7-10 is not understood. If the Examiner's reasoning for modifying the White reference in accordance with the teachings of the Ergun et al. reference are accepted, it is not seen what elements of claims 7-10 are not (allegedly) embodied in such a combination, and therefore the reason for additionally relying on the Kienzle III et al. reference is not understood.

Nevertheless, Appellants submit that merely having knowledge of a C-arm x-ray examination system, of the type disclosed in Ergun et al. reference, does not by itself provide a teaching, motivation or inducement to modify the White apparatus, with or without the teachings of Kienzle III et al., so as to acquire the data for producing the implant, and then to actually produce the implant, intra-operatively in the same medical interventional procedure.

As noted above, Appellants submit that the basic knowledge of the production of three-dimensional images using a C-arm apparatus by itself would deter a person of ordinary skill in the field of medical implant design from even considering the teachings of the Kienzle III et al. reference. Each of claims 7-10 explicitly states that the C-arm apparatus has the aforementioned range of movement of at least of 190°, and claims 7 and 9 explicitly state that the movement in this angle range occurs around the orbital axis of the C-arm x-ray apparatus, and claims 8 and 10 explicitly claim that the movement occurs around the angulation axis. Simply locating a reference disclosing a C-arm apparatus that is capable of such movement (which Appellants have never denied is known), does not provide a person of ordinary skill in the field of medical implant design with any new insight regarding the production of a medical implant in any context, much less in the context of undertaking data acquisition and production of the medical implant intra-operatively in the same medical interventional procedure.

CONCLUSION:

For the foregoing reasons, Appellants respectfully submit the Examiner is in error in law and in fact in rejecting claims 1-10 based on the teachings of the above references. Reversal of the rejections is therefore justified, and the same is respectfully requested.

This Appeal Brief is accompanied by a check for the requisite fee in the amount of $330.00.

Submitted by,

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CERTIFICATE OF MAILING

I hereby certify that an original and two copies of this correspondence are being deposited with the United States Postal Service as First Class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on March 18, 2004.

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APPENDIX "A"

1. A method for preparing an anatomical implant, comprising the steps of:

in a medical interventional procedure, intra-operatively generating a three-dimensional dataset of body tissue of a subject exhibiting a fault to be corrected by an implant from a series of two dimensional projections of the body tissue obtained from respectively different projection directions with a movable C-arm x-ray apparatus, by moving an x-ray source and a radiation receiver on a C-arm around said subject; and

in said medical interventional procedure, Intra-operatively preparing said implant adapted for introduction into said subject from said three-dimensional dataset.

2. A method as claimed in claim 1 comprising acquiring a three-dimensional dataset which represents a bone structure of said subject.

3. A method as claimed in claim 1 comprising intra-operatively preparing said implant with an automated device which is supplied with said three-dimensional dataset.

4. An apparatus for preparing an anatomical implant comprising:

a C-arm x-ray apparatus having a C-arm with an x-ray source and a radiation receiver mounted thereon, said C-arm x-ray apparatus, during a medical interventional procedure, intra-operatively generating a three-dimensional dataset of body tissue of a subject exhibiting a fault, to be corrected with an implant, by obtaining a series of two-dimensional projections of the body tissue from respectively different projection

directions by moving said C-arm, with said x-ray source and said radiation detector thereon, around the body tissue; and

an implant-producing device which intra-operatively produces said implant from said three-dimensional dataset, during said interventional medical procedure.

5. An apparatus as claimed in claim 4 wherein said dataset represents a bone structure, and wherein said implant is adapted to replace said bone structure.

6. An apparatus as claimed in claim 4 wherein said implant-preparing device is an automated device which is supplied with said three-dimensional dataset and automatically prepares said implant therefrom.

7. A method as claimed in claim 1 wherein said C-arm has an orbital axis, and wherein the step of moving an x-ray source and a radiation receiver on a C-arm around said subject comprises moving said x-ray source and said radiation receiver on said C-arm through at least approximately 190° around said orbital axis.

8. A method as claimed in claim 1 wherein said C-arm has an angulation axis, and wherein the step of moving an x-ray source and a radiation receiver on a C-arm around said subject comprises moving said x-ray source and said radiation receiver on said C-arm through at least approximately 190° around said angulation axis.

9. An apparatus as claimed in claim 4 wherein said C-arm has an orbital axis, and wherein said C-arm x-ray apparatus is operable to generate said three-dimensional dataset of body tissue by rotating said C-arm, with said x-ray source

and said radiation detector thereon, through at least approximately 190° around said orbital axis.

10. An apparatus as claimed in claim 4 wherein said C-arm has an angulation axis, and wherein said C-arm x-ray apparatus is operable to generate said three-dimensional dataset of body tissue by rotating said C-arm, with said x-ray source and said radiation detector thereon, through at least approximately 190° around said angulation axis.

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